MAY 1 5 2001

K010917

SECTION 11

Sunrise Medical

510(k) SUMMARY

K010917

Comparison of device characteristics to predicate

This device (Sunrise Medical Model Power Tilt and Recline System) has similar technological characteristics as the predicated device (Motion Concepts TRx-CG Power Tilt and Recline System). The Sunrise device and predicate device both use the Sunrise Medical Model S-626 power wheelchair as the base unit for the Power Tilt and Recline System. They use steel and aluminum in their frame and components, and standard material and covers for the slings and backs. A programmable microprocessor is used in the Sunrise Medical controller. The controller for the predicate is hard wired electronics.

Non-Clinical Testing

This device has been tested to appropriate ANSI/RESNA standards passing all test protocols.

Conclusion

Analysis of comparison of design, function and features of the Sunrise Medical Quickie Power Tilt and Recline System to the Motion Concepts Tilt and Recline System, together with the results of testing demonstrates the device to be substantially equivalent to the predicate in terms of meeting performance criteria and functioning as intended.

The Sunrise Medical Quickie Power Tilt and Recline System is substantially equivalent to the predicated device listed in this Summary and does not raise any issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2001

Mr. John Gerhold
Vice President of QA/RA
Sunrise Medical, Inc.
7477 East Dry Creek Parkway
Longmont, Colorado 80503

Re: K010917
Trade Name: Power Tilt and Recline System
Regulation Number: 890.3860
Regulatory Class: II
Product Code: ITI
Dated: March 23, 2001
Received: March 27, 2001

Dear Mr. Gerhold:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010917

Indications for Use

The Sunrise Medical Quickie Power Tilt and Recline System is appropriate for use by any individual who drives a Sunrise Model Quickie 626 power wheelchair and who desires or requires a change of position without having to utilize the services of an attendant. Needs for positioning changes include comfort, positioning and pressure relief or reduction.

Sunrise Medical makes no claim as to the therapeutic effectiveness of the products. Sunrise Medical only claims relate to the ability of the products to provide reliable power positioning.

510(k) number: Not assigned as of this time

Device name: Sunrise Medical Quickie Power Tilt and Recline System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010917

Prescription use (per 21 CFR801.109)

Over-the-counter use